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MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
KOROMA, BARBA M	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/998,059	OHLROGGE ET AL.	
	Examiner	Art Unit	
	Barba M. Koroma	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/18/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-10, and 17-26 in the paper filed September 7, 2004, is hereby acknowledged. Appropriate cancellation of non-elected claims is also acknowledged. Amended claims 17-35 are examined in this action.

2. In the response filed July 27, 2004, Applicants' indicated that the non-elected species be examined should SEQ ID No. 1 be found allowable (page 6, 4th paragraph). However, this was not an election of species since each nucleotide sequence is a patentably distinct invention, as discussed in the restriction requirement mailed June 30, 2004.

Information Disclosure Statement

3. It is improper to list the International search report in the IDS (PTO 1449 form). Correction is requested.

Specification

3. Specification is objected to and correction is requested for the following:

4. The specification fails to comply with 37 CFR 1.821-1.825. The examples on page 68, lines 24 and 25, page 69, lines 1-2, page 74, line 22, and figure 15-17, list sequences that do not recite the sequence identifiers of the sequences.

5. Figures 18 and 19 have labeled parts not referred to in the brief description. The brief descriptions should be amended to recite those labels. See 37 CFR 1.74.

6. The specification contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See for example, page 50, line 17; page 68, line 2; page 73 line 5, and page 74, line 4. See MPEP § 608.01.

7. On page 41, lines 12 and 25, there is no space between the word '*Arabidopsis*' and the words 'seeds' and 'detected', respectively.

8. On page 77 lines 11, the word 'by' should be omitted.

9. On page 77, the spelling 'promtores' is incorrect. Correction is required.

10. The specification lists the sections Example 3 as A-F and I-L, skipping G and H, (page 75-76). Correction is requested.

It is requested that Applicant examines and modifies entire specification so as to remove any additional errors that may be present therein. New matter must be avoided.

Claim Objections

11. Applicant is advised that should claims 17, 20, 21, 22, 23, 24, and 25, be found allowable, claims 19, 27, 30, 31, 32, 33, 34 and 35 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Claim 17 is directed to a method of producing a product of interest comprising a transgenic plant comprising a nucleic acid sequence encoding the product of interest. Claim 19 is directed to a method of expressing a nucleic acid sequence. However, part (a) of claim 19 states that the nucleic acid sequence encodes a product of interest. Other limitations of claims 17 and 19 are identical. Claims 20 and 27 encompass the same isolated DNA molecule. Lines 2-3 of claim 20 recite "seed specific promoter region". However, both claims recite identical Markush groups. Claims 21-26 and claims 30-35 recite the same limitations. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

12. In claim 17, line the word "which" should be removed.

Claim Rejections – 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 17 and 18-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to an isolated nucleic acid comprising a plant promoter region wherein the promoter region is a seed-specific promoter consisting of SEQ ID No. 1 and variants that are at least 80% identical to SEQ ID No.1; a method of producing a product or nucleic acid of interest in a plant seed comprising a transgenic plant and nucleic acid encoding a product of interest operably-linked to a promoter region, wherein the promoter region is a seed-specific promoter region selected from the group consisting of SEQ ID No. 1 and variants thereof that are at least 80%, 90%, or 95% identical to SEQ ID No. 1; an expression vector comprising the DNA molecule, a transgenic plant cell, a transgenic plant, and a transgenic seed.

The specification indicates that a cDNA library was constructed from *Arabidopsis thaliana* seed collections (example I, section , page 66, line 13). The cDNAs were sequenced, cloned in expression vector (example 1, section B), matched against existing libraries using BLASTX (section C, page 76). A list of expressed sequence tags (ESTs) was obtained (example 1, section D). The ESTs were PCR-amplified, arrayed, and subjected to hybridization analysis (sections A and B, example 2), using RNA extracted from various parts of *A. Thaliana* plants. Seed-specific promoter analysis was performed by comparing ESTs using BLAST against *Arabidopsis*

genomic sequences larger than 10kb using TAIR server. The promoter regions which were defined as those regions approximately 1kb upstream of ATG were selected for PCR amplification (section B, example 3), fused to promoterless β-GUS expression vector (example 3 - section C, page 74, lines 11-18), and used to transform *A. thaliana* plant tissues. Analysis of promoter activity was performed by histochemistry, time of expression, and quantitation of GUS expression levels, as a function of gene copy number and chromosomal insertion position effects (sections D through L, example 3).

The specification does not describe any variants of SEQ ID No.1 with at least 80%, 90%, or 95% sequence identity with SEQ ID No. 1. The specification defines variants or modified sequences as sequences with one or more nucleotide additions, deletions, or substitutions, which maintain the characteristic property of controlling or regulating seed-specific gene expression (page 46, lines 4-8). However, the specification does not describe all of the sequences of SEQ ID No. 1 essential to its promoter activity, or sequences of SEQ ID No. 1 that can be changed without abolishing promoter activity. SEQ ID No. 1 consists of 1150 nucleotide sequences. Therefore, a sequence that shares as little as 80% identity with SEQ ID No.1 will differ in 230 nucleotides. The specification does not provide any information concerning which 230 nucleotides of SEQ ID No. 1 may be changed, and to what they may be changed without affecting promoter activity. While the specification indicates that SEQ ID No.1 has a relatively seed-specific promoter activity, it does not indicate which regions are critical to seed specificity. In addition, the specification broadly defines a seed-specific promoter as one that controls or regulates gene expression in a seed or seed-tissue. The definition indicates that "P*referably,* expression of the

gene in seed tissue is greater than in non-seed tissue" (page 25, lines 4-8). This definition encompasses promoters that do not direct greater gene expression in seed tissues versus other tissues. The specification does not correlate the function of directing gene expression to a greater or equal extent in non-seed tissues versus seed tissues with the sequences of SEQ ID No. 1 or any variant thereof. Given the breadth of the claims encompassing nucleotide sequences that are at least 80% identical to SEQ ID No. 1, and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of polynucleotides encompassed by the claims.

14. Claims 17 and 18-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the promoter sequence of SEQ ID Nos. 1, does not reasonably provide enablement for variants thereof that are at least 80% identical to SEQ ID No. 1. that retain promoter activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with these claims.

The claims are broadly drawn to an isolated DNA molecule of SEQ ID No.1 and variants thereof that are at least 80%, 90%, or 95% identical to SEQ ID No.1, and a transgenic plant comprising a nucleic acid sequence encoding the protein of interest operably-linked to a promoter region, wherein the promoter region is a seed-specific promoter region, and a method of expressing a nucleic acid sequence of interest in a plant.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands,* 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The specification teaches that a cDNA library was constructed from *Arabidopsis thaliana* seed collections (example I, section, page 66, line 13). The cDNAs were sequenced, cloned in expression vector (example 1, section B) matched against existing libraries using BLASTX (section C, page 76). A list of expressed sequence tags (ESTs) was obtained (example 1, section D). The ESTs were PCR-amplified, arrayed, and subjected to hybridization analysis (sections A and B, example 2) using RNA extracted from various parts of *A. Thaliana* plants. Seed-specific promoter analysis was performed by comparing ESTs using BLAST against *Arabidopsis* genomic sequences larger than 10kb using TAIR server. The promoter regions defined as those regions approximately 1kb upstream of ATG were selected for PCR amplification (section B, example 3), fused to promoterless β-GUS expression vector (example 3 - section C, page 74, lines 11-18), and used to transform *A. thaliana* plant tissues. Analysis of promoter activity was performed by histochemistry, time of expression, and quantitation of GUS expression levels, as a

function of gene copy number and chromosomal insertion position effects (sections D through L, example 3).

The specification defines variants or modified sequences as sequences with one or more nucleotide additions, deletions, or substitutions, which maintain the characteristic property of controlling or regulating seed-specific gene expression on page 46, lines 4-8, but remains silent on a corresponding teaching of sequence modification by deletions, insertions, or substitutions of SEQ ID No.1 or variants thereof with at least 80%, 90%, or 95% sequence identity with SEQ ID No. 1, in which seed-specific promoter activity was retained. The specification does not teach all of the sequences of SEQ ID No. 1 that are essential to the retention of promoter activity in SEQ ID No. 1. In the case of SEQ ID No. 1 which consists of 1150 nucleotide sequences, a sequence that shares as little as 80% identity with SEQ ID No.1 will differ in 230 nucleotides. However, the specification does not provide any information concerning which 230 nucleotides of SEQ ID No. 1 may be changed, and to what they may be changed without affecting promoter activity. While the specification teaches that SEQ ID No.1 has a relatively seed-specific promoter activity, it does not teach which regions are critical to seed specificity. The specification also does not compare SEQ ID No.1 with any variant of SEQ ID No. 1 having at least 80%, 90%, or 95% sequence identity to SEQ ID No.1 in terms of nucleotide elements necessary for optimal promoter activity, under conditions that promote expression of seed-specific promoter activity. While the specification alludes to some eukaryotic promoters and enhancers as having a broad host range while others are functional in a limited subset of cell types (lines 13-15, page 23), it does not indicate for SEQ ID No. 1 or variants thereof, the properties of the sequence which limit

its expression to mainly the seed tissue. These missing data are critical because it has been established that even minor changes to a promoter can alter or abolish promoter activity (Kim et al. Plant Molecular Biology. 24:105-117; 1994, abstract lines 9-14, results section, pp105-113). Given the breadth of the claims encompassing SEQ ID No. 1 and variants thereof having at least 80%, 90%, or 95% sequence identity with SEQ ID No. 1, the lack of guidance of the specification as discussed above, the unpredictability in the art, and the plethora of possible permutations and combinations to which SEQ ID No. 1 and variants thereof can be subjected in order to determine how the sequences might be changed without affecting promoter activity, it would require undue experimentation by one skilled in the art to make and use the invention as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

15. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 recites the limitation "the product of interest" in line 4. There is insufficient antecedent basis for this limitation in the claim. It is suggested that the word "the" in the recitation be replaced with "a".

16. Claims 17-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 17-20 and 27 recite "seed-specific". The definitions of "tissue-specific"

on page 24, lines 4-8 and "seed-specific" on page 25, lines 4-10 are inconsistent. The definition on page 25 encompasses promoters that do not direct gene expression to a greater extent in seed tissues versus non-seed tissues. The definition on page 25 encompasses promoters that direct expression in seed, but also include those that direct equal or higher levels of gene expression in other tissues. It is not clear what is specifically meant by "seed-specific" as recited.

Claim Rejections – 35 USC 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 20, 27, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by EMBL database posting: accession number AL021749, *Arabidopsis* Thaliana DNA chromosome 4, BAC clone F2009, publication date: August 3, 1999, or by EMBL database posting: accession number AL161573, *Arabidopsis thaliana* DNA chromosome 4, Contig fragment No. 69, publication date: March 16, 2000.

Claims 20, 27, 28 and 29 recite an isolated DNA molecule comprising the promoter region, wherein the promoter region is a seed-specific promoter and is selected from the group consisting of SEQ ID No 1 and variants thereof that are at least 80%, 90%, and 95% identical to SEQ ID No. 1. The EMBL database sequence postings of accession numbers AL021749 and AL161573 are chromosome 4 genomic clones derived from *Arabidopsis thaliana* comprising SEQ ID No. 1.

Contact Information

18. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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bmk

ASHWIN D. MEHTA, PH.D.
PRIMARY EXAMINER